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(56) References cited:
EP-A- 0 240 316 **EP-A- 0 296 520**
US-A- 4 499 906 **US-A- 4 791 940**
US-A- 4 823 809 **US-A- 4 841 987**

• **S. MUKHERJEE, "The temperature of the
periodontal pockets", 1981, Department of
Periodontics, USA, Chicago, Journal of Clinical
Periodontology, 1981:8: 17-20.**

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Description

The present invention relates to an apparatus for diagnosing inflammatory conditions in connection with periodontitis, and the invention also involves a process for such diagnosis.

The loosening of teeth (periodontitis) is a bacterially caused inflammation in the attachment apparatus of the tooth (periodontium) which, if left untreated results in decomposition of the bone around the tooth (resorption) and of the tooth loosening its anchorage, the anchorage being ultimately lost. Periodontitis shall primarily be prevented by good oral hygiene but may also, after being established, be treated. This treatment will mainly be directed to interrupt the progress of the disease.

Practically all adults are to a greater or lesser degree subjected to the disease, and approximately 10% of the population in the industrialised world develop severe periodontitis resulting in partial or total loss of the teeth.

Periodontitis is initially a disease which to the patient lacks symptoms. However, the dentist can see early signs of an incipient disease development. The gum around the teeth become red, swollen and bleed easily, i.e. show signs of an inflammation. Simultaneously the pocket between tooth and gum will be subject to increased depth. In this pocket additional bacteria will accumulate and proliferate (plaque). Gradually the bacteria will calcify and calculus will form on the teeth. Synchronously with the formation of plaque the inflammation spreads in the attachment apparatus of the tooth and the bone surrounding the root of the tooth starts to decompose.

The methods available to the dentist to diagnose periodontitis is measuring the depth of the periodontal pocket around the tooth and registering the tendency for bleeding in connection herewith. However, this does not give a full measure of the degree of inflammation in the attachment apparatus of the tooth. Above all these measures give little guidance for judging how the disease will develop. They rather reflect what has already taken place.

One of the greatest problem in the treatment of periodontitis is to be able to predict around what teeth the periodontitis activity will increase. It has been found that the loss of supporting tissue around the teeth in periodontitis fluctuates, i.e. periods of low disease activity succeed periods of high activity. Early signs of this can be seen in the degree of inflammation in the environment of the teeth. An incipient increase of the degree of inflammation should be treated as soon as possible in order to save as much as possible of the anchorage of the tooth. The traditional methods (depth of periodontal pocket and bleeding tendency) in order to estimate this condition are not reliable. A deep periodontal pocket does not necessarily mean that the periodontal process is active. A healing process may have started. In the same manner a shallow periodontal pocket may not mean that the periodontal disease is inactive. Also a

deep pocket has once been shallow and it is very important to be able to predict which periodontal pockets are subject to deepening.

The cardinal symptoms of a topical inflammatory condition is calor (temperature increase), dolor (pain), rubor (redness) and tumor (swelling). Out of these the redness (bleeding in the periodontal pocket) and the swelling (in combination with decomposition of alveolar bone, i.e. measuring depth of periodontal pocket) have traditionally been used to diagnose periodontitis. However, these symptoms of periodontitis are not reliable measures for estimating the activity of the disease. Furthermore, it is not possible to estimate bleeding quantitatively. These traditional methods, measuring of pocket depth and bleeding tendency, to judge the activity of the periodontal process often give misleading results, particularly in an early stage of an active period. A deep periodontal pocket which is bleeding does not always mean that the process is active.

The use of temperature as a measurement for the activity of periodontitis is based on the fact that an inflammatory process in view of increased flow of blood results in an early temperature increase (before the depth of the periodontal pocket has increased). However, in the mouth the temperature varies between different areas. The gum is warmer the deeper in the oral cavity the measurement is made (32°C to 37°C). An absolute temperature scale to estimate the degree of inflammation is thus not possible to define. However, the surface temperature in the opening of the periodontal pocket is not affected by a possible inflammation at the bottom of the periodontal pocket.

The article "The temperature of the periodontal pockets", Journal of Clinical Periodontology, 1981, Vol. 8, pages 17-20, by S. Mukherjee, discloses measurements of the temperature and the depth of periodontal pockets by using a temperature probe and a separate graduated scale, respectively.

The present invention has for an object to provide an apparatus by means of which inflammatory conditions in connection with periodontitis can be diagnosed in a simple and reliable manner.

Another object of the invention is to provide a process for diagnosing the degree of inflammatory condition in connection with periodontitis, which process is based on an estimation of the exterior conditions around a so called periodontal pocket.

For these and other objects which will be clear from the following disclosure the invention which is defined in claim 1. It provides for an apparatus for diagnosing periodontitis in view of its inflammatory aspect, said apparatus comprising means for measuring and recording temperature in connection with a periodontal pocket. The apparatus for such diagnosis is provided with a measuring means with a graduated scale for measuring the depth of the periodontal pocket and in association herewith also provided with means for measuring and recording the temperature difference between the bottom and the mouth of the periodontal pocket.

The apparatus means for temperature measurement is suitably constituted by a probe which is connected to the measuring means in such a manner that the depth of the periodontal pocket can be recorded in connection with measuring the temperature at its bottom.

The temperature sensor or transducer, which is suitably positioned at the free end of the probe, can be of different types, of which examples are thermoelements, thermistors, semiconductor diodes and resistance transducers.

In a particularly preferred embodiment of the apparatus according to the present invention the probe and the measuring means are assembled to one unit. In an alternative embodiment of the apparatus according to the invention said means for temperature measurement may comprise a probe with two transducers displaceable relative to each other, the apparatus also including a measuring means with a graduated scale for measuring the depth of the periodontal pocket, one end of the probe being permanently connected to the measuring means at its free end, whereas the other transducer is movable along the scale so that the temperature difference between the bottom and the mouth of the periodontal pocket can be registered at the same time as the pocket depth is measured.

It is obvious for a man skilled in the art that the temperature simultaneously can be monitored at various levels of a tooth pocket by an array of sensors, or transducers.

The process for diagnosing inflammatory conditions in connection with periodontitis, is here based on considering the exterior conditions around a so called periodontal pocket. This process comprises the steps:

- a) measuring the depth of the periodontal pocket, i.e. the distance between the bottom and the mouth of the pocket;
- b) measuring the temperature difference between the bottom and mouth of the periodontal pocket; and
- c) determining the degree and development of the periodontitis in dependence of the parameters measured under step a) and step b).

In connection with the techniques according to the present invention it can be generally said that a temperature increase at the bottom of the periodontal pocket, more precisely a temperature difference of more than about 0.5°C between the mouth and bottom of the periodontal pocket, constitutes an early sign of the fact that the periodontal process is entering an active stage. A temperature difference of more than about 1°C shows that the process is established. The present invention thus provides for reliable diagnostic techniques which are based on simultaneous measurement of the temperature difference between the bottom and the mouth of the pocket and the depth of the pocket, and through said techniques one may thus verify whether the perio-

dontal process resides in an active stage and whether said process is established.

The invention will in the following be further described by non-limiting examples in conjunction with the appended drawings, wherein:

Fig. 1 shows diagrammatically the construction of an apparatus according to the present invention with its auxiliary equipment;

Fig. 2 shows diagrammatically the measuring transducer with associated probe;

Fig. 3 shows on a larger scale the distal probe part of the measuring transducer;

Fig. 4 shows diagrammatically a scheme on another embodiment of the invention;

Fig. 5 shows more in detail the display unit of the embodiment of Fig. 4;

Fig. 6 shows a diagram on the development of periodontitis over time as a function of the temperature difference between the bottom and the mouth of the periodontal pocket; and

Fig. 7 shows a corresponding diagram including the result of hygiene treatment.

EXAMPLE 1

Figure 1 shows diagrammatically the structure of the instrument in the form of a block diagram. In principle, the instrument consists of a manually held measuring transducer 1, which via a cable is connected to a recording unit consisting of an amplifier with filter 3, computer 5, display 7, printer 9 and a device 11 for voltage supply. In the amplifying unit 3 the amplification is adjusted in such a manner that a suitable signal size is obtained to computer 5. Said computer is of a conventional type and can be constituted for example by a Zilog Z80 with associated operational circuits and programmable memory. In this non-limiting example there has been chosen as a display 7 a liquid crystal display, since such device consume substantially less energy than a corresponding display of the light emitting diode type. If, however, the instrument is directly means-connected this latter type of better readability can advantageously be used.

The voltage supply unit 11 may consist of a rechargeable system with nickel-cadmium cells and associated charger. However, the instrument may also be connected directly to the mains. In both cases the voltage unit contains suitably arranged control circuits stabilizing the voltage through the other part of the electronic equipment. In Figs. 2 and 3 the manually held measuring probe 1 is shown more in detail. The measuring probe 1 in principle consists of a probe 13 attached to a handle 15 and the free distal end 17 which is shown in enlargement in Fig. 3. This free end 17 is at its tip provided with a temperature sensor or transducer 19 which through electrically leading cables 21 is connected with the recording unit of the instrument as described in connection with Fig. 1. The free end 17 of the probe 13 is

further provided with markings 23 enabling measurement of the depth of the periodontal pocket.

According to Fig. 2 the measuring probe is provided with a switch for activating the instrument.

The function of the instrument described is briefly the following.

The measuring probe 1 is placed with the free end 17 of probe 13 placed in the periodontal pocket which is subject to diagnosis, sensor or transducer 19 being positioned adjacent to the bottom of the pocket. The electronics are then activated by means of a switch 25. The temperature which is registered at the bottom of the periodontal pocket is measured by the computer, and when the signal has been stabilized the level is recorded and the operator is correspondingly informed for example by a short sound signal. The measured value can then as the case may be be registered with printer 9.

Then the measuring probe 13 with its free end 17 and sensor or transducer 19 is moved to the mouth of the periodontal pocket and the measuring procedure is repeated. By means of computer 5 the difference between the two temperatures measured is now calculated, said difference being shown on the display 7 of the instrument and may also be registered by printer 9.

In connection with measuring the temperature at the bottom of the periodontal pocket also the depth of said pocket is measured by means of the scale or marking 23.

By correlating the temperature difference measured and the depth of the periodontal pocket information whether the periodontal process is moving into an active stage and whether the process is established will be obtained in a simple manner. In accordance with the result obtained a suitable treatment regime can then be instituted.

EXAMPLE 2

The blockdiagram in Fig. 4 shows another preferred embodiment of the apparatus according to the present invention. The temperature probe with its sensor 31 is connected via a cable to an electronic unit 32 consisting of an amplifier with filter, computer and power supply. The temperature probe has a build-in-activator for registration of eventual bleeding in the tooth pocket. The display 33 unit as shown in Fig. 5 is connected via a cable to the electronic unit. The display has two groups 40, 41 of figures. One 40 for indication of the number of the tooth and another 41 for the display of the temperature difference between the mouth of the periodontal pocket and the bottom. Furthermore, there is an array of indicators to show the position in the tooth pocket and a reset-switch 42 to be able to start the measurements from the beginning. The registration of the temperature is activated by a footswitch 34.

As seen in Fig. 4 a remote display 35 and/or a printer 36 is also available to connect to the electronic unit.

The measuring procedure is as follows:

1. Press the "reset" button.
2. The probe 31 is placed into the bottom of the tooth pocket.
3. Activate the footswitch 34.
4. When a low frequency signal is heard the measurement procedure is completed.
5. Move to the mouth of the tooth pocket.
6. Activate the footswitch.
7. When the measuring period is completed a high frequency signal is heard.
8. The display shows the temperature difference and the indicator moves automatically to the next measuring site.

Registration of bleeding can be performed for the measured position by activating the probe. An indication 43 will appear on the display.

The advantage with this embodiment is that the probe could be held more firm since the measurement is activated by the footswitch.

EXAMPLE 3

Example of registration correlated to the development of periodontitis

Fig. 6 shows registrations of the initial temperature difference between the bottom and the mouth (t_d) of 30 periodontal pockets at the initial stage 30 periodontal pockets distributed among 4 patients and the subsequent change in anchorage of the tooth at the respective periodontal pocket measured after five months (a_d). The teeth around which the registrations have been made have all diagnosed periodontitis. A positive value of a_d means that the attachment has increased, whereas a negative value means loss of attachment, i.e. the periodontitis has progressed. Values of $t_d < 0.5^\circ\text{C}$ in the initial stage are seen only for periodontal pockets where a gain or no change of the attachment of the tooth has been registered. Average a_d in the range is 0.46mm, i.e. a gain of attachment. Values of $t_d \geq 0.5^\circ\text{C}$ but $< 1.0^\circ\text{C}$ have often resulted in a loss of tooth attachment. Average f_d in said range is -1.00mm. The most serious losses of tooth attachment are seen for $t_d \geq 1.0^\circ\text{C}$ having an average a_d in the range of -2.75mm, i.e. the periodontitis has developed.

EXAMPLE 4

Fig. 7 shows registrations of the initial temperature difference between the bottom and the mouth of 35 periodontal pockets (t_d) distributed among 6 patients and the subsequent change in anchorage of the tooth at the respective periodontal pocket (a_d) measured after 2 months. Only periodontal pockets with a temperature difference of more than 0.5°C ($t_d > 0.5^\circ\text{C}$) were selected. After registration of t_d , they were given hygiene treat-

ment with subgingival scaling. After 2 months change in periodontal anchorage was registered (a_d). By the treatment these periodontal pockets, which would have lost periodontal attachment according to Example 3 because of active periodontitis as indicated by $t_d > 0.5^\circ\text{C}$ instead gained or maintained their original level of anchorage, as an average $a_d = 0.77$ mm.

Claims

1. Apparatus for diagnosing an inflammatory condition relating to periodontitis, comprising means (1,3) for measuring and recording temperature in connection with a periodontal pocket, and measuring means (17) with a graduated scale (23) for measuring the depth of the periodontal pocket, characterized in that the means (1, 3) for measuring and recording temperature is assembled with the measuring means (17) into one unit, and in that it comprises means (5) for calculating the difference between the temperature measured in the bottom and at the mouth of the periodontal pocket.
2. Apparatus according to claim 1, characterized in that said means for temperature measurement is constituted by a probe (13) which is assembled into one unit with the measuring means (17) in such a manner that the depth of the periodontal pocket can be recorded in connection with measuring the temperature at its bottom.
3. Apparatus according to claim 1 or 2, characterized in that the probe (13) comprises a sensor or transducer of the type thermoelement, thermistor, semiconductor diode or resistance transducer.
4. Apparatus according to claim 1, characterized in that said means for temperature measurement comprises a probe (13) having two sensors or transducers movable relative to each other, and, one sensor or transducer of the probe (13) being permanently connected to the measuring means (17) at its free end, whereas the other sensor or transducer is movable along the scale so that the temperature difference between the bottom and the mouth of the periodontal pocket can be recorded at the same time as the pocket depth is measured.
5. Apparatus according to claim 4, characterized in that the probe (13) comprises two sensors or transducers of the type thermoelement, thermistor, semiconductor diode or resistance transducer.

Patentansprüche

1. Vorrichtung zum Diagnostizieren einer Entzündung im Zusammenhang mit Periodontitis, die eine Einrichtung (1,3) zum Messen und Aufzeichnen der Temperatur einer Periodontaltasche umfaßt, sowie

eine Meßeinrichtung (17) mit einer mit Gradeinteilung versehenen Skala (23) zum Messen der Tiefe der Periodontaltasche, **dadurch gekennzeichnet, daß** die Einrichtung (1,3) zum Messen und Aufzeichnen der Temperatur mit der Meßeinrichtung (17) zu einer Einheit zusammengebaut ist und daß sie eine Einrichtung (5) zum Errechnen des Unterschiedes zwischen der am Boden und der an der Öffnung der Periodontaltasche gemessenen Temperatur umfaßt.

2. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet, daß** die Einrichtung zum Temperaturmessen durch eine Sonde (13) gebildet wird, die mit der Meßeinrichtung (17) so zu einer Einheit zusammengebaut ist, daß die Tiefe der Periodontaltasche beim Messen der Temperatur an ihrem Boden aufgezeichnet werden kann.
3. Vorrichtung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** die Sonde (13) einen Sensor oder Wandler vom Typ Thermoelement, Thermistor, Halbleiterdiode oder Widerstandswandler umfaßt.
4. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet, daß** die Einrichtung zum Temperaturmessen eine Sonde (13) mit zwei Sensoren oder Wandlern umfaßt, die zueinander beweglich sind, und einer der Sensoren oder Wandler der Sonde (13) an seinem freien Ende fest mit der Meßeinrichtung (17) verbunden ist, während der andere Sensor oder Wandler entlang der Skala bewegt werden kann, so daß der Temperaturunterschied zwischen dem Boden und der Öffnung der Periodontaltasche zur gleichen Zeit aufgezeichnet werden kann, zu der die Tiefe der Tasche gemessen wird.
5. Vorrichtung nach Anspruch 4, **dadurch gekennzeichnet, daß** die Sonde (13) zwei Sensoren oder Wandler vom Typ Thermoelement, Thermistor, Halbleiterdiode oder Widerstandswandler umfaßt.

Revendications

1. Appareil de diagnostic d'une condition inflammatoire relative au périodonte, comprenant un dispositif (1, 3) de mesure et d'enregistrement de la température par rapport à une poche périodontique, et un dispositif (17) de mesure ayant une échelle graduée (23) de mesure de la profondeur de la poche périodontique, caractérisé en ce que le dispositif (1, 3) de mesure et d'enregistrement de la température est monté sous forme solidaire du dispositif (17) de mesure, et en ce qu'il comporte un dispositif (5) de calcul de la différence entre les températures mesurées au fond et à l'embouchure de la poche périodontique.

2. Appareil selon la revendication 1, caractérisé en ce que le dispositif de mesure de température est constitué par une sonde (13) qui est montée dans un ensemble avec le dispositif de mesure (17) de manière que la profondeur de la poche périodontique puisse être enregistrée lors de la mesure de la température à son fond. 5
3. Appareil selon la revendication 1 ou 2, caractérisé en ce que la sonde (13) comporte un capteur ou transducteur du type d'un thermoélément, d'une thermistance, d'une diode à semi-conducteur ou d'un transducteur résistif. 10
4. Appareil selon la revendication 1, caractérisé en ce que le dispositif de mesure de température comporte une sonde (13) ayant deux capteurs ou transducteurs mobiles l'un par rapport à l'autre, et un capteur ou transducteur de la sonde (13) est raccordé de manière permanente au dispositif de mesure (17) à son extrémité libre, alors que l'autre capteur ou transducteur est mobile le long de l'échelle afin que la différence de température entre le fond et l'embouchure de la poche périodontique puisse être enregistrée en même temps que la profondeur de la poche est mesurée. 15 20 25
5. Appareil selon la revendication 4, caractérisé en ce que la sonde (13) comporte deux capteurs ou transducteurs du type d'un thermoélément, d'une thermistance, d'une diode à semi-conducteur ou d'un transducteur résistif. 30

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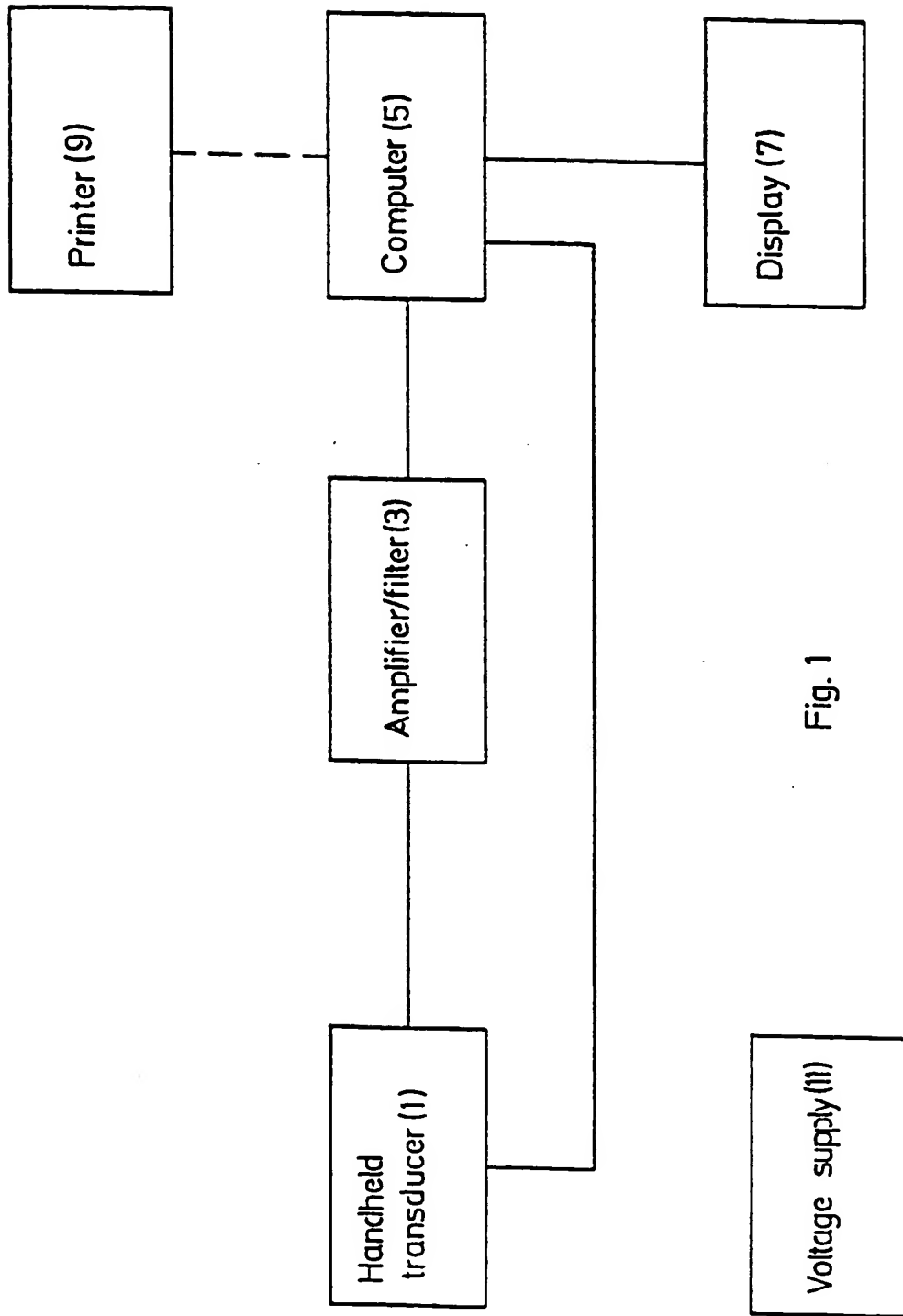
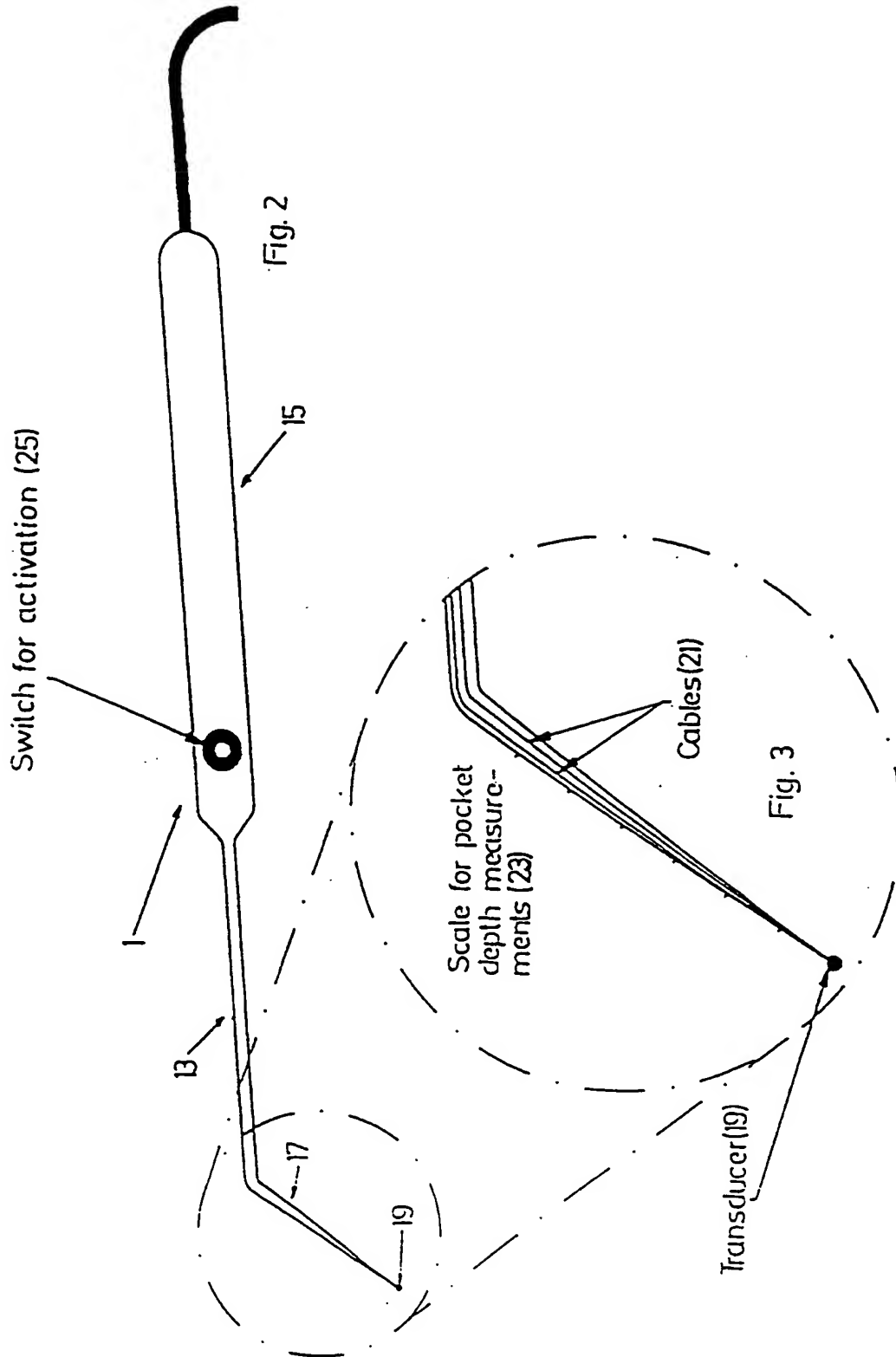


Fig. 1



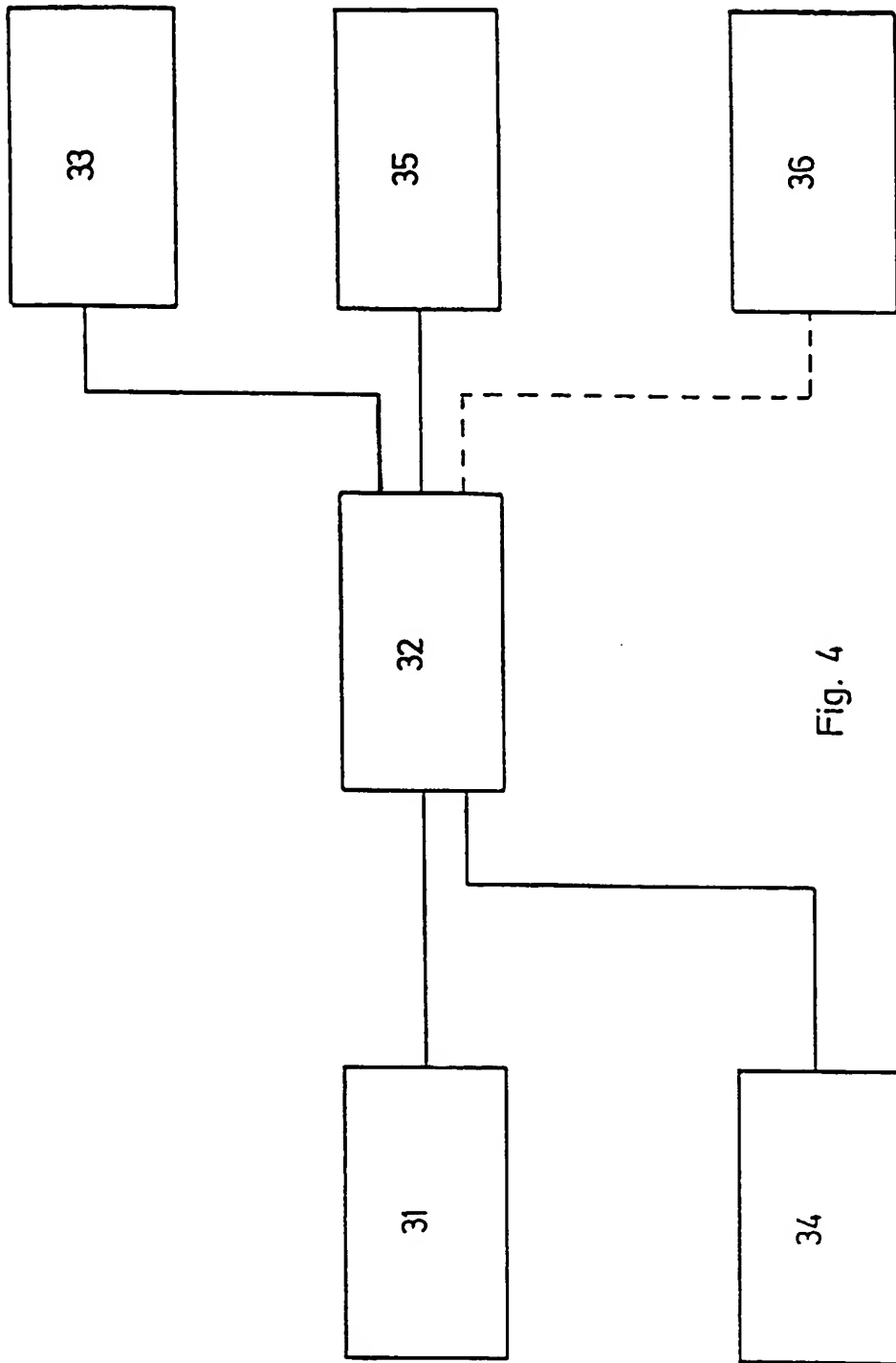


Fig. 4

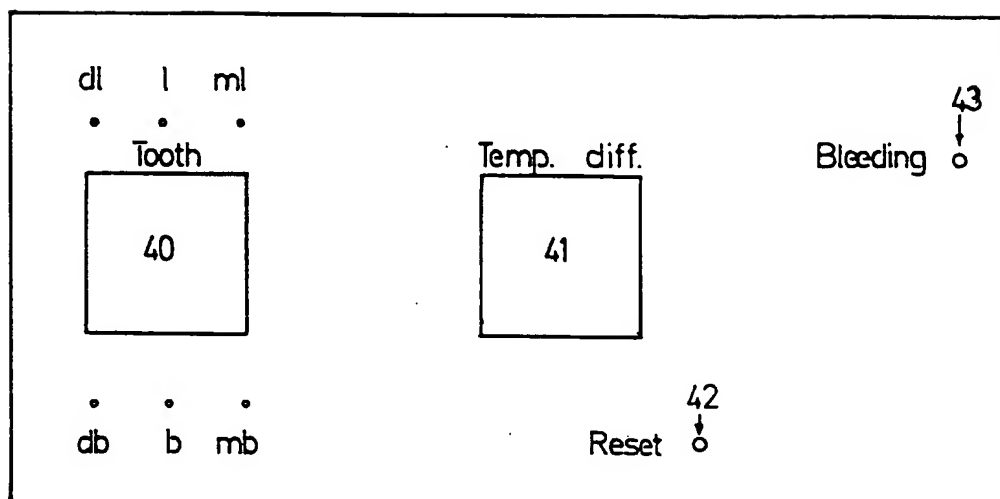


Fig. 5

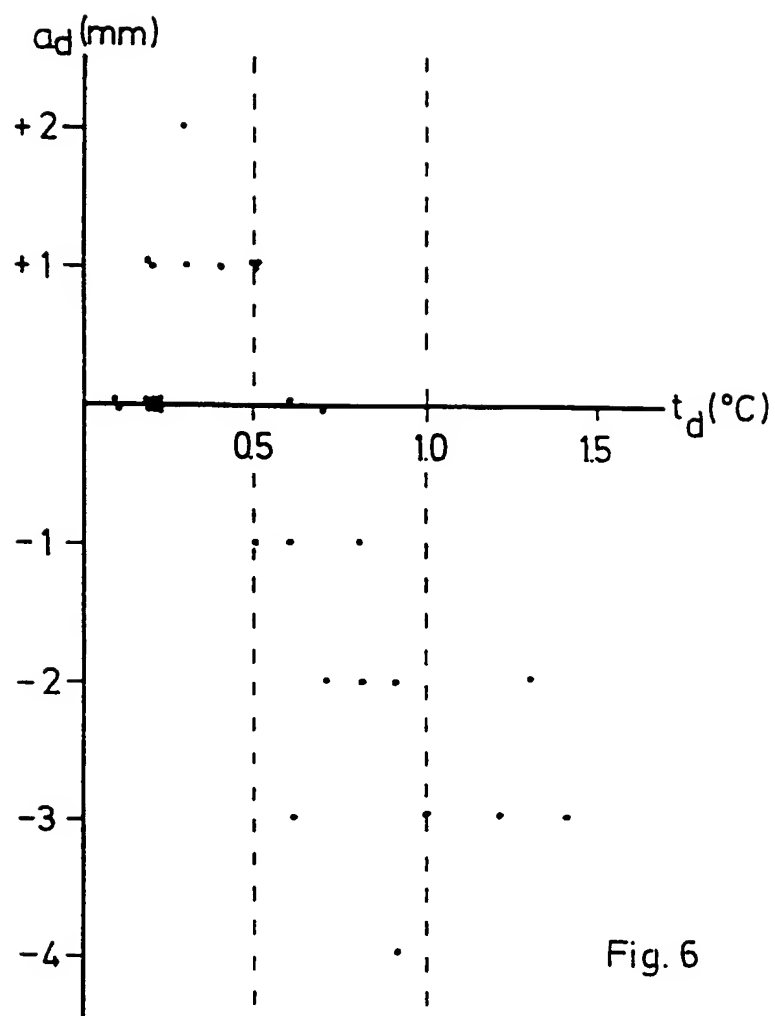


Fig. 6

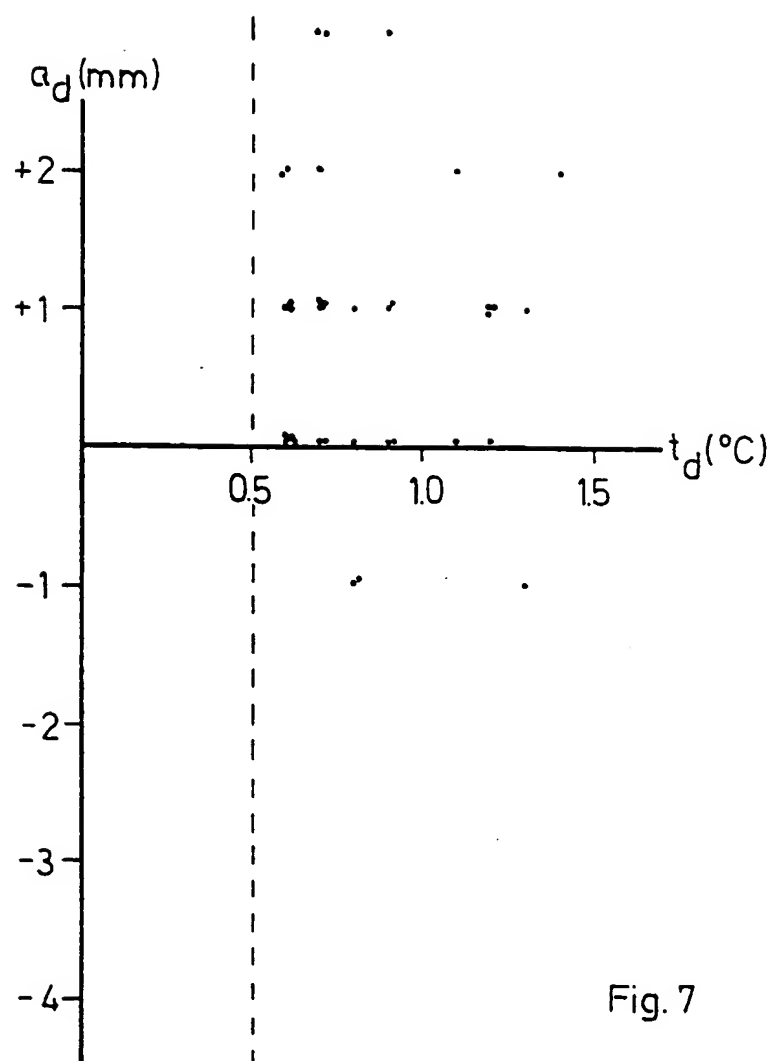


Fig. 7